REMARKS

Claims 1 – 9, 12 – 18, and 20 are currently pending. Claims 1 and 20 are the pending independent claims. In the Office Action, the Examiner rejected Claim 18 under 35 U.S.C. §112, first paragraph, as allegedly not enabled for "preventing all diseases." Claims 13-16 are rejected under 35 U.S.C. §112, second paragraph, as allegedly providing insufficient antecedent basis for the limitation "the obtained cores." Claims 12-14 are rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite. Claims 17 and 18 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,609,909 to Meyer et al. ("Meyer"). Also, Claims 1-9, 12-18, and 20 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 5,705,190 to Broad et al. ("Broad"), in view of the Ansel et al. publication in Pharmaceutical Dosage Forms and Drug Delivery Systems ("Ansel"). Finally, Claim 6 is objected to under 37 C.F.R. §1.75(c) as allegedly being of improper dependent form.

Claim 6 is hereby canceled without prejudice. Claims 1, 12, 13, 17, and 18 are amended to more particularly point out and distinctly define the claimed subject matter. Support for the amendment to Claim 1 may be found on page 5 of the Specification. Support for the amendments to Claims 12 and 13 may be found on page 8 of the specification. Support for the amendments to Claims 17 and 18 may be found on page 6 of the specification. No new matter is added into the case by any of the amendments.

Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the above amendments and following remarks.

I. The Enablement Rejection.

The Examiner contends that Claim 18 lacks enablement under Section 112, first paragraph. Specifically, the Examiner contends that the claim refers to "*preventing all diseases*" (emphasis from Office Action). However, Claim 18 does not purport to claim prevention of all diseases. Rather, Claim 18 (which is dependent from Claim 1) only covers treatment and prevention of those diseases treatable with the active ingredient

clarithromycin recited in Claim 1. Clearly, a person having ordinary skill in the art reading the claims would understand that Claim 18 relates only to diseases treatable by clarithromycin, and not, for example, the treatment or prevention of influenza, a virus not treatable with the antibiotic clarithromycin. This is further emphasized in the specification at the bottom of page 8: "e.g., if the active substance is clarithromycin, in the treatment and prevention of bacterial infections." Accordingly, a person of ordinary skill in the art reading the claims would be more than sufficiently apprised of how to practice the claimed subject matter. In view of this argument, it is respectfully submitted that the enablement rejection has been overcome and that the same should now be withdrawn.

II. The Lack Of Antecedent Basis Rejections.

Claim 13 (and dependent claims 14-16) are rejected under 35 U.S.C. §112, second paragraph, as allegedly providing insufficient antecedent basis for the term "the obtained cores." However, claims 12 and 13 are amended herein to provide proper antecedent basis for the terms used in Claim 13 (and Claims 14-16). Accordingly, it is submitted that the rejection of Claim 13-16 is overcome by the amendment and withdrawal of the rejection is respectfully requested.

III. The Indefiniteness Rejections.

Claims 12-14 are rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite for reciting the relative term "large." However, this term does not appear anywhere in Claims 12-14, thus it is respectfully submitted that the present rejection is not well taken and should be withdrawn.

IV. The Prior Art Rejections.

Finally, turning to the prior art, the Examiner contends that Claim 17 and 18 are allegedly anticipated by Meyer. However, the claims, as amended, recite only

formulations that are in tablet or capsule form. This limitation is not contemplated by Meyer, which only teaches, discloses, and suggests liquid suspensions of coated particles (Meyer, Col. 6, Lines 27-30), and not any type of tablet or capsule preparation of the pharmaceutical composition. Accordingly, Meyer cannot anticipate amended Claims 17 and 18 because the reference does not provide all of the elements and limitations of the claims. Withdrawal of the rejection is hereby respectfully requested.

Claims 1-9, 12-18, and 20 are further rejected as allegedly obvious over Broad in view of Ansel. With regard to Claims 1-9 and 12-18, no combination of the references teaches, discloses, or suggests that the micronized clarithromycin has a particle size of d(0.9) up to about 30μm (Page 5, Specification). In other words, amended Claim 1 recites that 90% of the micronized clarithromycin particles have a particle size of about 30μm or less. Broad does not disclose a micronized active ingredient, and Ansel is silent about the particle size of the micronized particles. Absent any specific information regarding particle size, the claims cannot be obvious from the cited art.

Claims 2-9 and 12-18 depend from Claim 1, and include all of the elements and limitations thereof. Accordingly, the combined references do not render any of Claims 1-9 and 12-18 obvious because they do not teach, disclose, or suggest all the elements and limitations of the claims.

With regard to Claim 20, the Office Action states that Broad does not expressly teach a polymer coating including polymers with the recited viscosity values (Page 12, Office Action). The Office Action goes on to assert that this deficiency of Broad is cured by the teaching of Ansel. Applicants respectfully disagree.

On page 11 (last sentence) of the Office Action, in reference to the aqueous film forming coating agents claimed herein, it is stated: "Since the agents [taught in Ansel] are the same as instantly claimed then they intrinsically have the same viscosity in the absence of evidence to the contrary." This is simply not true. Ansel provides a "laundry list" of components that may be used as tablet coating agents (Page 91, Ansel), but only the names of the components are given. No other properties, such as viscosity, are given.

The Examiner goes on to make the false assumption that since the names of the substances in Ansel and in the instant claims are the same (for example, hydroxypropyl methylcellulose), the physical properties (such as viscosity) of these substances must also be the same.

However, for example, hydroxypropyl methylcellulose (HPMC) is available in a wide range of both high and low viscosity forms, as evidenced by U.S. Patent No. 5,009,895 to Lui (see especially Claims 1-7). A person of ordinary skill in the art reading Ansel and Broad would have no reason to select the claimed polymers without any specific direction from the prior art as to what viscosities would be suitable for providing film coatings for the claimed clarithromycin tablets. Accordingly, the combination of Broad and Ansel cannot possibly render the Claim 20 obvious. Reconsideration and allowance of Claims 1-9, 12-18, and 20 are hereby respectfully requested.

V. The Objection to Claim 6 is Moot.

Since Claim 6 is now cancelled, the objection to the claim in the Office Action is moot.

In light of the foregoing, Applicants respectfully urge the Examiner to reconsider the application, to withdraw the rejections of Claims 1-9, 12-18, and 20, and to issue a notice of allowance at the earliest possible convenience.

It is further noted that these amendments are made in the interest of expeditious prosecution of the current application and while reserving the right to prosecute claims of a broader scope in one or more continuation applications.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our **Deposit Account No. 12-2355.**

Respectfully submitted,

LUEDEKA, NEELY & GRAHAM, P.C.

By: /J. David Gonce /

J. David Gonce
Registration No. 47,601

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P.O. Box 1871
Knoxville, Tennessee 37901
(865) 546-4305